DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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MAY 25 2000

The Honorable Martin Frost
House of Representatives
Washington, D.C. 20515-4324

Dear Mr. Frost:

Thank you for your letter of April 10, 2000, expressing your concerns regarding the Food and Drug Administration's (FDA or the Agency) planned actions with respect to ephedra. The Agency fully intends to solicit input from the consuming public and the industry as we proceed in our deliberations regarding the regulation of dietary supplements containing ephedra/ephedrine alkaloids. We are making every effort to be responsive to the comments contained in the August 4, 1999, GAO report with particular attention being paid to the quality of the information available on these products, including their use and safety as well as the openness and transparency of the Agency's deliberative process. Our February 25, 2000, letter to interested members of Congress outlined our next steps in this matter (copy enclosed).

Regarding release of the Adverse Event Reports (AERS), we believe that it is important and appropriate to provide interested parties with our expert review and evaluation of the data we have available at the same time we make the information publicly available. This provides interested persons with an opportunity to consider the views our in-house and consultant experts have on the information available to us at this time. The fact that there are opinions on the currently available information does not mean that FDA has predetermined any course of action until after we receive input on the public docket in response to our Federal Register notices (copies enclosed) and subsequent to a public meeting on this subject planned for later this year.

When FDA released the AERS on March 31, 2000, the criteria used by FDA to analyze the documents was made public. The Federal Register notice does not explain the criteria FDA used to categorize the AERS. This information is included in the

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Part II, section E, Appendices of the document that went to the public docket. We are enclosing a copy of those Appendices with the criteria FDA used to evaluate the new case series of adverse event reports. We encourage you to submit any comments you have on these criteria to the public docket. We are also forwarding your letter to the docket.

The Agency invited the major dietary supplement trade associations to participate in a telephone conference call on Friday, March 31, 2000, so that we could describe for them the public docket and Federal Register notices. We made it clear during the teleconference that this will be an open process; that all interested parties will be given time to review the Agency's data and initial analyses and to provide their own data, analyses, or other information before any action is taken by FDA. Industry is encouraged to provide their evaluation of the AERS to the Agency by submitting their independent assessment to the public docket.

Thank you again for contacting us about this matter. If you have further questions, please let us know.

Sincerely,

Timothy S. Hynes

for Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure
Dear Member letter
Federal Register notices
Appendices

cc: Docket Management Branch
(Docket #00N-1200)

MARTIN FROST
24th District, Texas

DEMOCRATIC CAUCUS
CHAIRMAN

RULES COMMITTEE

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House of Representatives
Washington, DC 20515

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April 10, 2000

Dr. Jane Hanney
Food and Drug Administration
5600 Fishers Ln
Rockville, MD 20857

Dear Dr. Hanney:

I wanted to share with you my concerns about the Food and Drug Administration's (FDA) intent to release the adverse event reports (AERs) which have been accumulated on the ephedra issue. I commend the FDA's decision to withdraw the proposed serving and duration limits on dietary supplements containing ephedra.

Now I urge you to develop a completely open and transparent public process for the review of all the available data. It is essential that the Agency propose and make public in advance the criteria that will define what is appropriate for reviewing ephedra products. I would also request that the Agency permit independent evaluation of any new AERs.

Thank you for your assistance in this matter.

Sincerely,

MARTIN FROST
Member of Congress

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Please reply to office checked

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